

# Role of CROs and KPOs/BPOs



Module 13 Topic 2

# Contract Research Map: India

- Approximately 404 medium to large CROs are present across India



<http://www.contractresearchmap.com/places/india>  
(29 Jul 2018)



# Contract Research Organization (CRO)

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Contract research organization (CRO) is a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.



## Why Outsource to CRO?

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- Thus apart from considering cost, Research organizers look for all the quality standards and expertise available before opting for CRO
- The clinical portion of the drug development constitutes the most labor-intensive and costly phase of drug development
- Besides Cost, often sponsors of the research seemingly don't find it apt to employ large permanent workforce for conducting research



# Why Outsource to CRO?

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- Sponsors may face problem of
  - sufficing the large number of employees in their premises and a quick recruitment of vast manpower is also a major obstacle.
  - All the labor-intensive work such as
    - monitoring,
    - auditing,
    - database management,
    - programming for listing and tables, and
    - statistical interpretation
    - are reasonably easy to outsource without the fear of any mishandling in Clinical Research workflow.





## CRO: Growth

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- CRO speaking literally refers to a person or an organization who is contracted to conduct clinical trials and duties with sponsor
- Over the last decade CRO market has witnessed a spurious rise worldwide with millions of workforce employed with them
- The figures that were \$1 billion for CROs in early 90's stands at around \$6 billion at present date.
- Among the global CRO market, India holds a market of \$300 to \$500 million in the field of Clinical Research Organization (CRO)



## CRO: Growth

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- CROs provide wide array of services in Clinical Research field
- They can either be specialized in any number of services that can be offered for Clinical Researches
- Besides Clinical Researches, CRO also provide development services for Non- Clinical like pharmaceutical, bioscience, medical devices industry, petrochemicals etc



# Major Services that CRO's provide

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- Site Management
- Clinical Trial Data Management
- Clinical Trial Project Management
- Clinical Trial Monitoring and Auditing
- Clinical Trial Logistics Services
- Clinical Supplies Manufacturing & Packaging/Labelling
- Central Lab Services
- Regulatory Affairs
- BA/BE Services
- Medical & Protocol Writing
- Education & training etc...





## Benefits with CRO

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- CRO is professionally equipped to provide the services for trials and is a safe and best choice for sponsors of study
- CROs can be easily relied for the study to be conducted with their coordination
- CRO can variedly conduct diverse task for Clinical study with competent and professional workforce
- CROs manages the study and Research more efficiently and cost-effectively, and maximize the benefits in time and profit of patient-protected products



# Benefits with Contract Research Organization

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- Fulfills the areas where sponsor organization is lacking like personnel's strength, technology, facility needed for specific Research without the actual increase of resources at sponsors end
- Cuts the cost tremendously as it is located at the location where monetary cost of resources is comparatively much less
- Time duration also gets reduced as CRO have the professional experience and has accessible resource, technology and facility that sponsor organization may not support



# Benefits with Contract Research Organization

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- CRO have more experience as they have direct links from other companies and also have the know-how & proficiency of conducting trials
- CRO has the expertise over the trends and basics of Regulatory authority and affairs in the native country
- CROs are aware of the issues that can evolve in the study and the methods to deal with them



# Selection of a CRO

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- Every aspect holds certain pros and cons if not handled properly. Similarly CRO can turn out disastrous if Sponsor of the researches doesn't make a smart and intelligent selection
- Its necessary for them to scrutinize every minutest detail associated with Contract Research Organization (CRO)



## Selection of a CRO

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- As CRO comes from entirely a different country, sponsors often may not have the idea about the culture of the country
- Thus it's not at all advisable to leave everything on CRO stake. It's the duty of sponsors to Research properly and extensively before choosing a CRO
- The CRO must be selected with respect to the nature of the project and whether or not CRO has expertise in it?





# Selection of a CRO

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- Sponsors and Organizers of the Study must take it into account to evaluate the past record and all the history in terms of trials CRO has conducted
- If necessary sponsors can also crosscheck and cross verify directly from the client of the CRO
- It's sponsor's duty to see that their project is compatible with CRO services and they must ensure the related aspects to the project



# Key points to be checked at the time of selection

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- Well equipped Infrastructure and Facility
- Must be technologically advanced and should support the latest software for labs and site management
- Qualified Researchers and professionally qualified & experienced management team
- Good rapport with regulatory authorities
- Knowledge of Regulatory affairs & guidelines such as GCP
- Should have a good database of qualified volunteers and patients





## TOP 10 CROs 2018

			Revenues, 2017 (USD billions)	Income Ratio, 2017	Expense Ratio, 2017	Service portfolio (units)
	01	Laboratory Corporation of America Holdings (Covance)	10,441	12,14%	87,86%	31
	02	Quintiles IMS Holdings, Inc	9,739	13,44%	86,56%	92
	03	Syneos Health	2,672	8,90%	91,10%	42
	04	Paraxel International Corporation	2,441	4,40%	95,60%	79
	05	PRA Health Sciences	2,259	9,69%	90,31%	27
	06	Pharmaceutical Product Development (PPD)	1,900	5,00%	95,00%	44
	07	Charles River Laboratories International Inc (CRL)	1,857	6,65%	93,34%	4
	08	ICON Public Limited Corporation	1,758	16,84%	83,16%	15
	09	Wuxi Aptec	1,011	12,00%	88,00%	5
	10	Medpace Holdings, Inc	0,436	8,96%	91,03%	2

<https://www.igeahub.com/2018/03/15/top-10-global-cros-2018/>



# References

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- [http://www.fermish.com/contract\\_research\\_organization/contract\\_research\\_organization\\_benefits.htm](http://www.fermish.com/contract_research_organization/contract_research_organization_benefits.htm)  
– (29/7/2018; 9:35am)
- <https://www.igeahub.com/2018/03/15/top-10-global-cros-2018/>  
– (29/7/2018: 12.55 pm)



# What is BPO and KPO

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- **Business Process Outsourcing or BPO** is the outsourcing of any segment/ process/ function of the business organization to an outside organization.
- The major cause behind the outsourcing of business process is to reduce costs and maximize efficiency.
- The focus is made on the process, i.e. the process is predetermined, and the provider has to bring consistency and productivity in the assigned processes.





# What is BPO and KPO

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- **Knowledge Process Outsourcing or KPO** refers to the assignment or transfer of knowledge plus information related process to another organization.
- KPO firms perform high-level tasks for which highly skilled personnel are required by the firms.
- It is an extended version of BPO.
- It requires in-depth knowledge, domain expertise, judgment and interpretation power of the workers, who are capable of applying their knowledge because the work entails decision making on specific issues.



# Services of KPOs to Pharma Industries

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- Pharma KPO provides its partners with a broad range of solutions that are aimed at reducing costs while optimizing business performance
- Pharma KPO focuses in the field of pharmaceutical and medical knowledge process outsourcing
- Services that require general or specialized knowledge in the pharmaceutical, pharmacological, and medical science



# Services of KPOs to Pharma Industries

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- The growth of the global healthcare and pharma industry has been hindered by high development costs, lower number of unique molecules discovered, increased development timelines and dynamic market conditions
- Currently, the outsourcing of research and development work seems to be a viable option available to mitigate the risks involved
- India offers a strong advantage in clinical research and trials due to the following factors:
  - Availability of a large and diverse patient pool
  - Reduced time for data analysis
  - Availability of large skilled workforce



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# Services of KPOs to Pharma Industries

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- KPOs mainly offer research and backend work.
- KPOs use their employees expertise to carry out high-end processes like
  - Valuation
  - Research
  - Investment researches
  - Patent filing
  - Legal and insurance claims
  - Medical diagnoses and reports
  - Clinical trial and many other profiles depending on the industry the KPO caters to





# References

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- Sameer Rastogi, Ajay Pal Singh & Tarun Virmani. Knowledge Processing Outsourcing (KPO): Opportunities in Pharmacy Research and Development. Indian Journal of Drugs, 2015, 3(3), 71-78

